

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SETTE *et al.*

Appl. No. 09/412,863

Filed: October 5, 1999

**For: Inducing Cellular Immune
Responses to Human Immunodeficiency
Virus-1 Using Peptide and Nucleic Acid
Compositions**

Confirmation No. 1200

Art Unit: 1644

Examiner: Schwadron, R.B.

Atty. Docket: 2060.0040005/HCC/PAC

Third Supplemental Information Disclosure Statement

Director of the United States
Patent and Trademark Office
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Third Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Second Supplemental Information Disclosure Statement filed on January 31, 2003 in connection with the above-captioned application. A copy of each document is also provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates

should not be construed as an admission that the information was actually published on the date indicated.

For Documents AT36, AT38, and AT44, Eriksson, K., *et. al*, Ibe, M., *et al.*, and Rudén *et al.*, respectively, the month of publication could not be determined, and therefore has been omitted.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

This Third Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Helene C. Carlson
Agent for Applicants
Registration No. 47,473

Date: 8/7/03

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FORM PTO-1449

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INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
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	AA						
	AB2	5,763,158	06/09/1998	Bohannon			02/06/1997
	AC2	5,837,249	11/17/1998	Heber-Katz <i>et al.</i>			10/20/1993
	AD2	5,932,224	08/03/1999	Chisari			06/06/1995
	AE2	6,001,349	12/14/1999	Panicali <i>et al.</i>			02/22/1995
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO5	WO 97/34617 A1	09/25/1997	WIPO			Yes No
	AP5	WO 99/45954 A1	09/16/1999	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	33	Aleanzi, M., <i>et al.</i> , "Epitope Contiguous Chains and Antibody Recognition in HIV-1 Synthetic Peptide Antigens," <i>J. Mol. Recognit.</i> 9:631-638, John Wiley & Sons, Ltd. (September-December 1996)
	AS	33	Broliden, P.A., <i>et al.</i> , "Specific Synthetic Peptides for Detection of and Discrimination Between HIV-1 and HIV-2 Infection," <i>J. Acquir. Immune Defic. Syndr.</i> 4:952-958, Raven Press, Ltd. (1991)
	AT	33	Brown, L.E., <i>et al.</i> , "Synthetic peptides representing sequences within gp41 of HIV as immunogens for murine T- and B-cell responses," <i>Arch. Virol.</i> 140:635-654, Springer-Verlag (April 1995)

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	AL6	WO 99/58658 A2 & A3	11/18/1999	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>34</u>	Chiodi, F., <i>et al.</i> , "Site-Directed ELISA With Synthetic Peptides Representing the HIV Transmembrane Glycoprotein," <i>J. Med. Virol.</i> 23:1-9, Alan R. Liss, Inc. (1987)
AS	<u>34</u>	Choppin, J., <i>et al.</i> , "Analysis of Physical Interactions between Peptides and HLA Molecules and Application to the Detection of Human Immunodeficiency Virus 1 Antigenic Peptides," <i>J. Exp. Med.</i> 172:889-899, The Rockefeller University Press (1990)
AT	<u>34</u>	Dadaglio, G., <i>et al.</i> , "Epitope recognition of conserved HIV envelope sequences by human cytotoxic T lymphocytes," <i>J. Immunol.</i> 147:2302-2309, The American Association of Immunologists (1991)

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	AR	<u>35</u>	Davis, D., <i>et al.</i> , "The immunodominance of epitopes within the transmembrane protein (gp41) of human immunodeficiency virus type 1 may be determined by the host's previous exposure to similar epitopes on unrelated antigens," <i>J. Gen. Virol.</i> 71:1975-1983, Society for General Microbiology (1990)
	AS	<u>35</u>	Divita, G., <i>et al.</i> , "Inhibition of Human Immunodeficiency Virus Type 1 Reverse Transcriptase Dimerization Using Synthetic Peptides Derived from the Connection Domain," <i>J. Biol. Chem.</i> 269:13080-13083, The American Society for Biochemistry and Molecular Biology, Inc. (May 1994)
	AT	<u>35</u>	Döpel, S-H., <i>et al.</i> , "Fine mapping of an immunodominant region of the transmembrane protein of the human immunodeficiency virus (HIV-1)," <i>J. Virol. Methods</i> 25:167-177, Elsevier Science Publishers B.V. (1989)

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	AR	36	Ebenbichler, C.F., <i>et al.</i> , "Human Immunodeficiency Virus Type 1 Activates the Classical Pathway of Complement by Direct C1 Binding through Specific Sites in the Transmembrane Glycoprotein gp41," <i>J. Exp. Med.</i> 174:1417-1424, The Rockefeller University Press (1991)
	AS	36	Eddleston, M., <i>et al.</i> , "Molecular Mimicry Accompanying HIV-1 Infection: Human Monoclonal Antibodies That Bind to gp41 and to Astrocytes," <i>AIDS Res. Hum. Retroviruses</i> 9:939-944, Mary Ann Liebert, Inc. (October 1993)
	AT	36	Eriksson, K., <i>et al.</i> , "Systematic identification of T-cell activating epitopes on the human immunodeficiency virus type 1 envelope glycoprotein gp120 in primates immunized with synthetic peptides," <i>Vaccine</i> 11:859-865, Buitenworth-Heinemann, Ltd. (1993)

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	AR	<u>37</u>	Gevorkian, G.G., <i>et al.</i> , "Solid-phase synthesis of a peptide comprising the 605-611 disulfide loop of gp41, transmembrane glycoprotein of human immunodeficiency virus type 1 (HIV-1)," <i>Org. Preparations and Procedures Intl.</i> 27:375-377, Organic Preparations and Procedures, Inc. (February 1995)
	AS	<u>37</u>	Gevorkian, G., <i>et al.</i> , "Serologic Reactivity of a Synthetic Peptide from Human Immunodeficiency Virus Type 1 gp41 with Sera from a Mexican Population," <i>Clin. Diagn. Lab. Immunol.</i> 3:651-653, American Society for Microbiology (November 1996)
	AT	<u>37</u>	Gnann, Jr., J.W., <i>et al.</i> , "Synthetic Peptide Immunoassay Distinguishes HIV Type 1 and HIV Type 2 Infections," <i>Science</i> 237:1346-1349, American Association for the Advancement of Science (1987)

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	AR	<u>38</u>	Hernandez, H.J., <i>et al.</i> , "Evolution of reactivity of sera from HIV-1 patients to synthetic gp41 (598-609) and analogues," in <i>Peptides 1992: Proceedings of the Twenty-Second European Symposium</i> , Schneider, C.H., and Eberle, A.N., eds., ESCOM Science Publisher B.V. Leiden, Netherlands, pp. 887-888 (June 1993)
	AS	<u>38</u>	Hummel, R.-P., <i>et al.</i> , "Distinction of HIV-1 and HIV-2 infection using novel synthetic lipopeptide-conjugates as antigens in ELISA," in <i>Peptides 1988: Proceedings of the 20th European Peptide Symposium</i> , Jung, G., and Bayer, E., eds., Walter de Gruyter & Co., Berlin, Germany, pp.686-688 (1988)
	AT	<u>38</u>	Ibe, M., <i>et al.</i> , "Role of strong anchor residues in the effective binding of 10-mer and 11-mer peptides to HLA-A*2402 molecules," <i>Immunogenetics</i> 44:233-241, Springer-Verlag (1996)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>39</u>	Isagulians, M.G., <i>et al.</i> , "Linear Fusion of HIV-1 B-Epitopes and Heterologous T-Cell Epitopes. II. Multiparametric Assay of Immunogenicity of Composite Peptides in Rabbits," <i>Biochemistry (Mosc)</i> 61:878-885, MAIK Hayka/Interperiodica Publishing (July 1996)
	AS	<u>39</u>	Isagulians, M.G., <i>et al.</i> , "HIV-1 epitopes exposed by hybrid hepatitis B core particles affect proliferation of peripheral blood mononuclear cells from HIV-1 positive donors," <i>Immunol. Lett.</i> 52:37-44, Elsevier Science B.V. (August 1996)
	AT	<u>39</u>	Isagulians, M.G., <i>et al.</i> , "Expression of HIV-1 Epitopes Inserted into the Nucleocapsid Protein of Human Hepatitis B Virus," <i>Biochemistry (Mosc)</i> 61:393-403, MAIK Hayka/Interperiodica Publishing (March 1996)

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	AR	<u>40</u>	Ivanov, V.T., <i>et al.</i> , "Synthesis of biotinylated peptides and their application in immunometric immunoassay," in <i>Peptides - Chemistry and Biology: Proceedings of the Twelfth American Peptide Symposium</i> , Smith, J.A., and Rivier, J.E., eds., ESCOM, Leiden, Netherlands, pp. 734-735 (February 1992)
	AS	<u>40</u>	Ivanov, V.S., <i>et al.</i> , "Study of the antigenic structure of human immunodeficiency viruses by means of synthetic peptides," <i>Bioorg. Khim.</i> 18:784-793, Nauka (June 1992)
	AT	<u>40</u>	Johnson, R.P., <i>et al.</i> , "Induction of a Major Histocompatibility Complex Class I-Restricted Cytotoxic T-Lymphocyte Response to a Highly Conserved Region of Human Immunodeficiency Virus Type 1 (HIV-1) gp120 in Seronegative Humans Immunized with a Candidate HIV-1 Vaccine," <i>J. Virol.</i> 68:3145-3153, American Society for Microbiology (May 1994)

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	AR	<u>41</u>	Jurcevic, S., <i>et al.</i> , "Role of polymorphic residues of human leucocyte antigen-DR molecules on the binding of human immunodeficiency virus peptides," <i>Immunology</i> 87:414-420, Blackwell Science, Ltd. (March 1996)
	AS	<u>41</u>	Krchňák, V., and Vágner, J., "Color-Monitored Solid-Phase Multiple Peptide Synthesis Under Low-Pressure Continuous-Flow Conditions," <i>Pept. Res.</i> 3:182-193, Eaton Publishing Company (1990)
	AT	<u>41</u>	Lauritzen, E., <i>et al.</i> , "Peptide dot immunoassay and immunoblotting: Electrophoresis from aluminum thin-layer chromatography plates and isoelectric focusing gels to activated nitrocellulose," <i>Electrophoresis</i> 14:852-859, VCH Verlagsgesellschaft mbH (September 1993)

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	AR	<u>42</u>	Libonatti, O., <i>et al.</i> , "Evaluation of a gp41 synthetic peptide for detection of antibodies anti-HIV1," <i>Acta. Physiol. Pharmacol. Latinoam.</i> 40:93-98, Asociacion Latinoamericana De Ciencias Fisiologicas (1990)
	AS	<u>42</u>	Lombardi, V., <i>et al.</i> , "Epitope Specificity, Antibody-Dependent Cellular Cytotoxicity, and Neutralizing Activity of Antibodies to Human Immunodeficiency Virus Type 1 in Autoimmune MRL/lpr Mice," <i>J. Infect. Dis.</i> 167:1267-1273, University of Chicago Press (June 1993)
	AT	<u>42</u>	Mathiesen, T., <i>et al.</i> , "Fine analysis of intrathecally synthesized anti-HIV IgG1-4 by peptide mapping," <i>J. Neurol. Sci.</i> 100:31-36, Elsevier Science Publishers B.V. (1990)

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	AR	<u>43</u>	Mendes, N.F., <i>et al.</i> , "Reactivity patterns of HIV-1 positive sera with a gp41 synthetic peptide," <i>Cienc. Cult.</i> 46:472-474, Sociedade Brasileira Para O Progresso Da Ciencia (September/December 1994)
	AS	<u>43</u>	Mutch, D., <i>et al.</i> , "Comprehensive T-Cell Epitope Mapping of HIV-1 <i>env</i> Antigens Reveals Many Areas Recognized by HIV-1-Seropositive and by Low-Risk HIV-1-Seronegative Individuals," <i>J. Acquir. Immune Defic. Syndr.</i> 7:879-890, Raven Press, Ltd. (September 1994)
	AT	<u>43</u>	Neurath, A.R., <i>et al.</i> , "B cell epitope mapping of human immunodeficiency virus envelope glycoproteins with long (19- to 36-residue) synthetic peptides," <i>J. Gen. Virol.</i> 71:85-95, Society for General Microbiology (1990)

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	AR	<u>44</u>	Norrby, E., <i>et al.</i> , "Immunochemistry of the dominating antigenic region Ala ⁵⁸² to Cys ⁶⁰⁴ in the transmembranous protein of simian and human immunodeficiency virus," <i>J. Immunol.</i> 143:3602-3608, The American Association of Immunologists (1989)
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FORM PTO-1449

THIRD SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
2060.0040005/HCC/PACAPPLICATION NO.
09/412,863APPLICANT
SETTE *et al.*FILING DATE
October 5, 1999GROUP
1644

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>45</u>	Shuixing, X., <i>et al.</i> , "Chemical Synthesis of a peptide representing immunodominant epitope on gp41 protein of human immunodeficiency virus type 1," <i>Chin. J. Virol.</i> 8:372-374, Chung-Kuo Wei Sheng Wu Hsueh Hui (December 1992)
	AS	<u>45</u>	Štys, D., <i>et al.</i> , "Time dependence of immunoresponse of different epitopes of gp41 and its relation to the structure of short peptide fragments of gp41," <i>Collect. Czech. Chem. Commun.</i> 60:1054-1064, Nakladatelství Československé Akademie Věd (May 1995)
	AT	<u>45</u>	Thielans, N.M., <i>et al.</i> , "Further Characterization of the Interaction between the C1q Subcomponent of Human C1 and the Transmembrane Envelope Glycoprotein gp41 of HIV-1," <i>J. Immunol.</i> 151:6583-6592, The American Association of Immunologists (December 1993)

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	AR	<u>46</u>	Turánek, J., <i>et al.</i> , "Adjuvant effect of liposomes and adamantylamide dipeptide on antigenicity of entrapped synthetic peptide derived from HIV-1 transmembrane region glycoprotein gp41," <i>Immunol. Lett.</i> 39:157-161, Elsevier Science B.V. (February 1994)
	AS	<u>46</u>	Vahne, A., <i>et al.</i> , "Immunizations of monkeys with synthetic peptides disclose conserved areas on gp120 of human immunodeficiency virus type 1 associated with cross-neutralizing antibodies and T-cell recognition," <i>Proc. Natl. Acad. Sci. USA</i> 88:10744-10748, National Academy Press (1991)
	AT	<u>46</u>	Wahren, B., <i>et al.</i> , "HIV-1 Peptides Induce a Proliferative Response in Lymphocytes from Infected Persons," <i>J. Acquir. Immune Defic. Syndr.</i> 4:448-456, Raven Press, Ltd. (1989)

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	AR	<u>47</u>	Warren, R.Q., <i>et al.</i> , "Synthetic Peptides Define the Fine Specificity of the Human Immunodeficiency Virus (HIV) gp160 Humoral Immune Response in HIV Type 1-Infected Chimpanzees," <i>J. Virol.</i> 64:486-492, American Society for Microbiology (1990)
	AS	<u>47</u>	Wild, C., <i>et al.</i> , "A synthetic peptide inhibitor of human immunodeficiency virus replication: Correlation between solution structure and viral inhibition," <i>Proc. Natl. Acad. Sci. USA</i> 89:10537-10541, National Academy Press (November 1992)
	AT	<u>47</u>	Yamada, M., <i>et al.</i> , "Common Immunologic Determinant between Human Immunodeficiency Virus Type 1 gp41 and Astrocytes," <i>J. Virol.</i> 65:1370-1376, American Society for Microbiology (1991)

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